

IV. Remarks

A. Drawings

Presently, the drawings are objected to because the Examiner contends they do not show each and every feature of the claimed invention. Applicants respectfully request reconsideration in light of the Disclosure. Applicants have amended Figure 1 to more clearly show the door, in an embodiment.

The Examiner contends that the phrase "indirectly or directly open connection to the channel and is closed from the outside after preloading" is not shown in the drawings. However, reference to page 5, line 11-26 of the specification clearly shows that Applicants' disclosure is sufficient. The specification states that the "closing off and opening up of the chamber can be by simple displacement of the plunger ... a door which automatically opens upon full withdrawal of the plunger, or any suitable mechanical, electronic or optical means.. .." Accordingly, the specification describes various embodiments of a structure to close-off the chamber. Furthermore, Figure b1 does show a closed chamber 7 when the plunger 5 is not withdrawn. The figure clearly illustrates an embodiment wherein chamber 7 is closed, the solid line represents a closed chamber 7. Accordingly, Applicants respectfully request reconsideration of the rejection.

As for the Examiner's contention that the phrase "the periphery of the plunger defining a chamber", Applicants question the accuracy of the Examiner's statement.

Claims 1, 9, and 10 all state "the periphery of the plunger defining a channel", not a chamber. Webster's New World Dictionary, Third College Edition, defines "periphery" as outside surface or surrounding space. Further "defines" is defined to mean "sets the boundaries or traces the outline of." Therefore, the periphery of the plunger, the outside surface of the plunger, fits within the channel, all of which is disclosed in the figures.

B. 35 USC §112, 1st ¶ Rejections

Claim 1 stands rejected under 35 USC §112, 1st ¶, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. The Examiner states that he is unclear to what the Applicants are claiming with the phrase "and is closed from the outside after preloading." Applicants respectfully request reconsideration in light of this response.

Applicants have removed the limitation of "from the outside," thereby broadening the scope of the Claim. No estoppel should result from this amendment.

The Examiner further states that the specific structures for the door assembly of an embodiment is missing or unclear. Applicants respectfully assert that a door is a structure well known in the art. The embodiment depicted in Figure 1 already illustrates how the door is closed after preloading. Therefore, Applicants have disclosed a door and

the structure is not missing or unclear. Accordingly, Applicants respectfully request reconsideration.

C. 35 USC §112, 2nd ¶ Rejections

The Examiner has rejected Claim 1 under 35 USC §112, 2nd ¶ as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner specifically contends that Claim 1 is missing essential structural cooperative relationships between elements. Applicants have amended Claim 1 to remove reference to "from the outside." Such amendment is believed to cure this rejection. No estoppel should result from said amendment because a limitation has been removed.

D. Rejections Under 35 USC §102

1. the '324 patent

Claims 9 and 10 stand rejected under 35 USC §102(b) as being anticipated by US Pat. No. 5,405,324 (hereinafter referred to as the '324 patent). The Examiner contends that the '324 patent discloses an implantation device comprising a hollow needle and a body adjoining the needle, the body comprising an elongated part extending along the same axis as the needle, a plunger that can be displaced within the elongated part and the needle, the periphery of the plunger defining a channel in the elongated part and a chamber capable of holding an implant characterized in that the chamber is positioned

radially outside the channel and has a directly or indirectly open connection to the channel, the plunger being capable of closing off and opening up the chamber by being displaced, as well as where the implantation device has a chamfered tip and where the plunger has a chamfered tip profile capable of blending with the needle tip profile.

Applicants respectfully request reconsideration in light of this response.

. The '324 patent does not disclose a device that is closed after preloading and does not hold an implant. Accordingly, Applicants respectfully request removal of the rejection and allowance of Claim 1 and its dependant Claims to issue. Further, the '324 patent does not disclose a chamber (7) for an implant (8) of the present invention. The '324 patent discloses a cup shaped cavity (3) having an opening in the bottom thereof which gives access to the bore (4) which is in line with the hollow needle (1) with the same diameter. (Column 5, lines 63-67 of the '324 patent). The cup shaped cavity (3) of the '324 patent is used, as is referenced in the instant application, of Applicants invention, for loading an implant or medicament in the chamber *during* operation of the device for implantation into the patient. The chamber (7) of the instant application is specifically claimed as being capable of holding an implant. A definition for holding an implant can be found on page 5 of the originally submitted application lines 21-26 wherein it states that "the implant contained therein, i.e., held, can be displaced into the channel on or after the moment that the required space therein has become available by withdraw of the plunger." The device of the '324 patent does not 'hold' the implant. Accordingly, the '324 patent does not anticipate the devices of the instant application. There are distinct differences.

2. the '613 patent

Claims 1, 3, 5, 7, 8, 9, and 10 stand rejected under 35 USC §102(b) as being anticipated by US Pat. No. 5,562,613 (hereinafter referred to as the '613 patent). The Examiner contends that the '613 patent discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber, wherein the needle is chamfered, and wherein the outside is closed after preloading. Applicants respectfully request reconsideration of the rejection in light of this response.

The Examiner refers to Figures 3 and 6 of the '613 for support that the outside is closed after preloading. Applicants request reconsideration. Reference to Figure 3 illustrates a device wherein a drug is placed in a notch 44. See the '613 patent, Col. 3, l. 56 to Col. 4, l. 65. The drug pellet is disposed on the platform provided on piston 28 by the piston notch 24. See the '613 patent Col. 3, l. 67 to Col. 4, l. 3. Applicants' invention specifically claims a chamber that is positioned radially outside the channel. The '613 patent discloses a notch in the line of the channel, not radially outside. Therefore, the '613 patent does not disclose Applicants' invention. Accordingly, Applicants respectfully request reconsideration of the rejection and that the rejection be withdrawn.

3. the '158 patent

Claims 1, 3, 5, 7, 8, 9, and 10 stand rejected under 35 USC §102(b) as being anticipated by US Pat. No. 1, 655, 158 (hereinafter referred to as the '158 patent). The

Examiner contends that the '158 patent discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber, wherein the needle is chamfered, and wherein the outside is closed after preloading. However, Applicants' Claims particularly claim a door. A door is not disclosed by the '058 patent. Therefore, Applicants respectfully request reconsideration of the rejection, in light of this response.

E. Rejections under 35 USC §103

1. the '158 in view of the '324

Claims 1, and 3-10 stand rejected under 35 USC §103(a) as being unpatentable over the '158 patent in further view of the '324 patent. The Examiner contends that the '158 patent differs only in that it does not disclose a hormonal implant. The Examiner further contends that the '324 patent discloses a hormonal implant.

The Examiner then contends that it would have been obvious to one of ordinary skill in the art to combine the '158 patent and the '324 patent because the Examiner further contends that it is well-known in the art to use different medicaments with implants. Applicants respectfully request reconsideration in light of this response.

As stated above, however, the '158 patent does not disclose a door, as claimed by Applicants' invention. Accordingly, the combination of the two is Applicants' invention. Therefore, Applicants respectfully request the rejection be withdrawn.

2. the '613 in view of the '324

Claims 1 and 3-10 stand rejected under 35 USC §103(a) as being unpatentable over the '613 patent in further view of the '324 patent. The Examiner contends that the '613 patent discloses Applicants' invention except that the implant is hormonal. The Examiner further contends that the '324 patent discloses a hormonal implant. The Examiner then states that it would have been obvious to one of ordinary skill in the art to combine the teachings of the '324 patent and the '613 patent to arrive at Applicants' invention. Applicants respectfully request reconsideration of the rejection in light of this response.

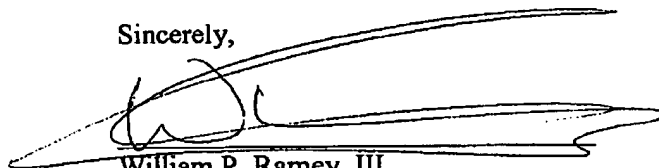
As stated above, reference to Figure 3 of the '613 patent illustrates a device wherein a drug is placed in a notch 44. See the '613 patent, Col. 3, l. 56 to Col. 4, l. 65. The drug pellet is disposed on the platform provided on piston 28 by the piston notch 24. See the '613 patent Col. 3, l. 67 to Col. 4, l. 3. Applicants' invention specifically claims a chamber that is positioned radially outside the channel. The '613 patent discloses a notch in the line of the channel, not radially outside. Therefore, the '613 patent does not disclose Applicants' invention. Additionally, the '324 patent does not disclose a device that is closed to the outside. Accordingly, the combination of the two is Applicants' invention. Therefore, Applicants respectfully request the rejection be withdrawn.

IV. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Please call the below undersigned attorney for any

assistance in securing allowance of this application. Please charge deposit account number 02-2334 for any required fees.

Sincerely,

A handwritten signature in black ink, appearing to be "W. Ramey, III", written over a horizontal line.

William P. Ramey, III
Reg. No. 44,295

Akzo Nobel Pharma Patent Department
405 State Street
P.O. Box 318
Millsboro, DE 19966
Tel: (302) 933-4034
Fax: (302) 934-4305

